# EXHIBIT E

IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION

Master File No. 2:12-MD-02327

MDL NO. 2327

JOSEPH R. GOODWIN
US DISTRICT JUDGE

THIS DOCUMENT RELATES TO:

Theresa England v. Ethicon, Inc., et al.
Case No. 2:15-cv-06967

- - -

OCTOBER 22, 2019

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Deposition of LENNOX HOYTE, MD, held at Morgan & Morgan, PA, 20 North Orange Avenue, Suite 1600, Orlando, Florida 32801, commencing at 11:57 a.m., on the above date, before Joan L. Pitt, Registered Merit Reporter, Certified Realtime Reporter, and Florida Professional Reporter.

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INDEX

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EXHIBIT INDEX





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THE COURT REPORTER: Raise your right hand, please. Do you swear or affirm the testimony you give will be the truth, the whole truth, and nothing but the truth.

THE WITNESS: I do.

THE COURT REPORTER: Thank you.

LENNOX HOYTE, MD, called as a witness by the Defendants, having been first duly sworn, testified as follows:

DIRECT EXAMINATION

BY MR. THOMAS:

Q. We're going to do three of these today, Doctor, so if it seems awkward, we're going to do the same thing we did last one, so bear with me.

State your name for the record, please?

A. Lennox Hoyte.

Q. And, Dr. Hoyte, we've just spent a couple hours talking about another one of the plaintiffs in this case, Ms. Ashbrook. You're an expert witness also in the case involving Theresa England?

A. Correct.

(Hoyte Exhibit No. 1 was marked for identification.)



BY MR. THOMAS:

Q. And just because these might go to different places, I'll mark as Deposition Exhibit No. 1 your CV that you provided to us. Is that a complete CV?

A. Yes. It has my name spelled right.

Q. Good. I neglected to ask you this in the Ashbrook deposition. Will you update your CV now to include that 2006 abstract?

A. I'm going to add that as soon as I get home. Do you have an extra copy?

Q. I do.

A. I can take that with me?

Q. Yeah, you sure can.

Okay. I'm not going to go through your CV -- I didn't last time -- any more than I have. Anything else you'd like to add about your CV?

A. Not that far back.

Q. Okay. And I have -- somewhere. I thought I was ready to do this.

You received a notice of deposition in this case?

A. Yes.

MR. THOMAS: And same materials in the same box that we talked about before in Ashbrook, Joe?

Page 6

MR. TARASKA: Yes. Yes.
MR. THOMAS: Okay. Do you have the billing records for the England case?
MR. TARASKA: Yes. There you go.
(Hoyte Exhibit No. 2 was marked for identification.)
BY MR. THOMAS:
Q. I'm going to mark your billing records for the Theresa England case as Deposition Exhibit No. 2. Two-page exhibit.
(Discussion off the record.)
BY MR. THOMAS:
Q. Let me show you what's been marked as Deposition Exhibit No. 2.
A. Yes, sir.
Q. And these have been provided to you by your counsel and represented to be the billing records for the Theresa England case; is that accurate?
A. That is correct.
Q. And so the deposition that you reviewed for England July 2019, would that have been the implanting physician, do you know?
A. That's the patient.
Q. Okay. You reviewed the --

Page 7

A. That's what I --
Q. -- the plaintiff?
A. That's what I believe, yes.
Q. Okay. Good. And 14 hours for review of the medical records?
A. That is correct.
Q. Prolift, TVT-O IFUs, two hours and a half?
A. Correct.
Q. It took you seven hours to do the expert report?
A. Correct.
Q. For a total of $16,500?
A. Correct.
Q. And that's dated August 9, 2019.
Then we have a September 25, 2019. You reviewed Ethicon's expert report?
A. Correct.
Q. For two hours?
A. Correct.
Q. And you billed for that?
A. Correct.
Q. Are you current with plaintiff's counsel for your bills?
A. Same as the last.

Page 8

Q. Are they paid?
A. These -- everything I've submitted they've paid.
Q. Okay.
A. Actually, I think there's one outstanding.
Q. And what work have you done since your last time entry on the bill?
A. So let's see. This is Ms. England.
Q. That's right.
A. She was a Dr. Yang patient, I believe.
Q. Correct.
A. So Yang's deposition, reviewed my draft report, prepare for the deposition, review of the medical records, did my best to understand the story of the case.
Q. And about how many hours have you spent since your last entry on Exhibit 2?
A. I don't have that tabulated.
Q. Do you have a ballpark guesstimate?
A. I don't.
Q. Did you say you reviewed Dr. Yang's deposition?
A. Again, I believe she's the implanter for Mrs. England, so I believe the answer is yes.
Q. Do you have a recollection of anything of

Page 9

significance in Dr. Yang's deposition that affected your opinions in this case?
A. No.
(Hoyte Exhibit No. 3 was marked for identification.)
BY MR. THOMAS:
Q. Doctor, Deposition Exhibit No. 3 is the report that counsel's provided to us for this case. Do you recognize that as your report?
A. I do.
Q. Is Exhibit No. 3 a complete statement of the opinions you're prepared to give in this case?
A. As I said before, there is one item pertaining to the uncertainty of the patient's prognosis that I need to clarify.
Q. Okay. Anything else?
A. The uncertainty of her prognosis, yes.
Q. Is there anything else that you care to add to it?
A. I believe that's it, and I reserve the right to add things as more information becomes available.
Q. Do you have plans to do any work at this point?
A. Based on the information I have, I don't have any plans, based on the information I have as of today.

Page 10

Q. Okay. Again, we're here for three depositions today: Messina, Ashbrook, as well as this case, England. And I'm not going to repeat a lot of the questions I asked in Ashbrook, and I hope to do the same for Messina to make this as short a proceeding as we possibly can. But all the answers from Ashbrook apply to England and Messina and all the way around. Does that make sense?

MR. TARASKA: Yes.

MR. THOMAS: Okay.

BY MR. THOMAS:

Q. Doctor, as I look at Exhibit No. 3, as I looked at Exhibit No. 3, this deals primarily with the surgical procedure on November 22, 2006, where Ms. England received an anterior Prolift, a TVT-O, and a posterior native tissue repair; is that fair?

A. Procedure No. 1 on 11/22/2006. Anterior Prolift rectocele repair, TVT-O, and cystoscopy.

Q. Okay. And what was the nature of the rectocele repair, the posterior repair?

A. It was a so-called native tissue repair using stitches and the patient's own tissue to fix the posterior wall vaginal bulge.

Q. Okay. And if Ms. England presented to you

Page 11

today with the symptoms that she presented with in 2006, is it fair to understand that you would have performed this procedure using the Desara retropubic sling and a laparoscopic sacrocolpopexy?

A. So let's look at her complaint first. So I would have started looking at her symptomatology. I'd begin by -- I'm a tertiary referral center, so that means the patient comes to me with specific complaints. If she complained -- if she came to me with complaints of a vaginal bulge and urinary incontinence and I evaluated her and demonstrated that she had urodynamic stress incontinence and either symptomatic Stage II cystocele or rectocele or Stage III, bothersome cystocele and rectocele, I would have offered her a retropubic sling and very likely a sacrocolpopexy, unless she had outstanding apical support, which, if she did, I would have offered her an anterior posterior repair with native tissue.

Q. Okay. Are you able to tell from your review of the medical records in this case from 2006 whether she presents with a situation where you'd recommend a sacrocolpopexy or the native tissue repair?

A. There is no pelvic organ prolapse quantitation evaluation here, so it's difficult for me to say, so I

Page 12

have to go based on the presenting doctor's examination of what she characterized as a Grade II rectocele and Grade II cystocele, symptomatic, and the patient's complaint of urinary incontinence.

Q. Well, all we have is the medical records; correct?

A. That's what I see here.

Q. Okay. And based upon the medical records, would you recommend a native tissue repair or a sacrocolpopexy?

A. Based on her symptomatic third-degree cystocele, if it were an isolated cystocele, I would offer a native tissue repair. If she had apical descent, I would offer a sacrocolpopexy.

Q. Are you able to tell whether she had apical descent or not?

A. There's no mention of apical descent in this report that I have here.

Q. If you had this patient today and she did have indications for a sacrocolpopexy, would you have done it laparoscopically or abdominally?

A. The abdominal sacrocolpopexy can be performed open, laparoscopically or robotically. My preference is a robotic sacrocolpopexy.

Page 13

Q. Was robotic sacrocolpopexy available in 2006?

A. 2006 was probably the beginnings of the margins of it. Laparoscopic would have been available in 2006. I was still performing open sacrocolpopexies, so that's probably what she would have gotten if she were my patient and she met criteria.

Q. And an open sacrocolpopexy uses mesh?

A. It does use abdominally placed mesh.

Q. And is it polypropylene mesh?

A. Yes, sir.

Q. And in 2006, do you recall what kind of mesh you were using for the placement of -- for the repair of -- strike that.

Do you recall what kind of mesh you were using in 2006 for your open abdominal sacrocolpopexies?

A. I do not recall.

Q. Did you ever use Gynemesh PS?

A. It would have been a precut Y graft, and so I don't know -- I don't recall who I was using at the time for that.

Q. Was it polypropylene?

A. Yes.

Q. Was it large pore?

A. Yes.

Page 14

Q. When you say "large pore," do you have a number in mind?
A. 1 millimeter.
Q. At least 1 millimeter, or was it 1 millimeter, do you know?
A. Give or take 1 millimeter.
Q. Okay. That's a satisfactory pore size for you for what you're trying to do with sacrocolpopexy?
A. That is my understanding, correct.
Q. Well, your understanding. I'm asking what your preference is, what you --
A. Large pore, lightweight, synthetic polypropylene mesh. Currently it's 21 gm/m2, made by Caldera. It's called Vertessa Lite. There were other manufacturers that made similar pore size and weight. I'm not sure exactly the weight.
Q. Okay. Have you ever heard of a Caldera T-Line midurethral sling?
A. No.
Q. Do you recall what midurethral sling you were using in 2006?
A. No, I don't.
Q. Were you using a midurethral sling in 2006?
A. Yes.

Page 15

Q. Polypropylene?
A. Yes.
Q. Large pore?
A. For synthetics, I don't recall, but I think it was large pore.
Q. In 2006, did you have a preference for a certain kind of synthetic midurethral sling?
A. I think 2006 was about 13 years ago, and I used a retropubic sling at that time that was synthetic that, as I recall, had adequate pore size.
Q. But you don't recall what it was?
A. I do not.
Q. In your practice today, are you able to choose the manufacturer's product that you want to use, or do you have to do what the hospital says you can do?
A. Well, I think it's a combination, that if the hospital has a material that I don't feel comfortable using for one reason or another, I would go to them and tell them what I wanted. I'm fortunate in that all the hospitals I go to have the Caldera systems, and that's what I feel comfortable using based on the pore size, the use, the experience, and the characteristics.
Q. Where were you practicing medicine in 2006?
A. Tampa General Hospital.

Page 16

Q. I'm sorry?
A. Tampa General Hospital.
Q. Thank you. Do you know whether in 2006 the hospital made the decision of the mesh that you used for sacrocolpopexy and midurethral slings or whether you had the choice?
A. Well, I was fortunate in 2006 in that we started the urogynecology program in the state of Florida, in fact, at the hospital, at Tampa General, and we told them what we wanted and they went and found it.
Q. Okay.
A. I just can't remember which one it was.
MR. THOMAS: All right. Let me go off the record for a second, please.
(Recess from 12:13 p.m. until 12:16 p.m.)
BY MR. THOMAS:
Q. As before, Doctor, on page 8 of your report you set out a methodology -- on page 13 of your report, you set out a methodology that you use when you evaluate, diagnose, and treat a person with mesh-related complications?
A. Yes.
Q. You usually rely on an interview with the patient. You've not talked with Ms. England; correct?

Page 17

A. I have not.
Q. You usually have a review of her personally documented history. You don't have her personally documented history, but you do have her medical records?
A. I have her medical records.
Q. It says you reviewed her medical records -- you have that -- and a detailed clinical examination when possible. You have not examined Ms. England; fair?
A. I have not, and I want to point out that this paragraph relates to when I evaluate patients clinically. This was not a clinical evaluation for the purposes of treatment with this patient. This was for the purpose of evaluating her prognosis and her treatment options.
Q. Okay. The next sentence says: "I use the information that I obtained from these modalities to determine the cause, treatment plan, and prognosis for the patient's presenting complaint."
Fair?
A. Correct.
Q. Okay. Now, you reviewed the operative report for the November 22, 2006, procedure?
A. Correct.
Q. Do you see anything remarkable about the

Page 18

procedure in itself?
A. It says the procedure was an anterior Prolift and rectocele repair and a TVT-O procedure with cystoscopy.
Q. Do you have any criticisms or complaints about the care and treatment provided by the implanting surgeon on November 22, 2006?
A. I do not.
Q. As far as you can tell from your review of the medical records, she did everything she was supposed to do to implant the anterior Prolift?
A. It looks like she followed the IFU.
Q. And as far as you can tell from your review of the medical records, she did everything she was supposed to do for the implantation of the TVT-O?
A. It looks like she did.
Q. And there are different kinds of native tissue repairs, aren't there?
A. Well, it depends on what you're repairing.
Q. Well, the posterior repair for the rectocele that was done on Ms. England, is there anything unusual about the nature of the repair that was done on November 22, 2006?
A. It looks like a posterior colporrhaphy to me.

Page 19

Q. Within the standard of care in 2006?
A. I would say yes, based on what I can see.
Q. Anything different about what she did in 2006 than what you would do in a native tissue repair in 2019?
A. Well, you do the posterior dissection, you take the mucosa off, you identify the defect, and you close it, and then you close the mucosa. That's how it's done.
Q. So she did everything in 2006 as you'd do it today?
A. That's how it's done, correct.
Q. Do you agree that there were no complaints from Ms. England related to this procedure from November 22, 2006, until March 26, 2004?
A. 12/15/2006 feeling something sharp sticking out at Postop Day 4. Postop Week 4. Sex not painful. Just some itching afterwards. No defects. History of a kidney stone. Stent placed. Unrelated. Kidney stone. Hot flashes. Normal vaginal fault. We're up to 2010. Vaginal dryness 2014. Urinary urgency. Eight years postoperatively is when we begin to see symptoms, and the exam documents that in 3 of 2014.
Q. That's my point. March 26, 2014, following the

Page 20

November 22, 2006, surgery is the first complaint by Ms. England related to the implant; is that fair?
A. That I would relate to the implant, and it's not surprising, correct.
Q. Okay. And she presents with vaginal dryness and urinary urgency?
A. That's what the complaint is listed as.
Q. Do you have a reason to disagree with that?
A. That's what I said.
Q. You said it's "listed as."
A. That's what I listed. Then that means I agree.
Q. Okay. Thank you.
A. Not trying to be difficult, sir.
Q. Neither am I, I assure you.
A. Yeah.
Q. Is vaginal dryness a symptom of implant for -- a Prolift implant or a TVT-O implant?
A. No.
Q. What's the cause of vaginal dryness?
A. So as women enter menopause, the vaginal tissues, which are normally -- which are extremely sensitive to estrogen, estrogen levels drop in the menopause, and when the estrogen levels drop, the vaginal tissue thins out. Women experience that as

Page 21

vaginal dryness. Some people experience that with reversible pain with intercourse due to the atrophy or dryness.
Q. Does vaginal dryness also contribute to pelvic pain?
A. Pain with intercourse is what I said.
Q. I understand that.
A. Not necessarily pelvic pain.
Q. But unrelated to dyspareunia, can vaginal dryness contribute to pelvic pain?
A. Not so much pain, but pressure. Women report a feeling of pressure that is remedied when you treat them with an appropriate course of vaginal estrogen.
Q. And is the urinary urgency that's reported on March 26, 2014, related to the implant in 2006?
A. It could be related to the implant, or it could be related to the vaginal dryness. Those are both possibilities.
Q. No way to tell from your review of the medical records?
A. Until you treat it with vaginal estrogen. One's cured. The other one's not.
Q. Okay. What's remarkable about her exam in March 2014?

Page 22

A. There was a ridge effect in the anterior wall and there was a tender anterior wall with bleeding to speculum examination. There was an irregular surface and mesh palpable just below surface beginning to erode along suture line, midline.
Q. Can the atrophic vaginal walls and vaginal dryness contribute to the bleeding?
A. It could, to bleeding on speculum. That's one -- certainly a possibility. So can mesh erosion.
Q. Okay. And is the plan an appropriate recommendation for the conditions with which she presented?
A. The plan was listed as starting vaginal estrogen and following up in three months. It's what I would have done.
Q. Seen by Dr. Halcomb on December 3, 2014, and there's a palpable mesh through the anterior compartment wall and palpable mesh through the -- twice. Is that because there's two findings of that, or is that just a mistake?
A. Cut and paste. Fingers a little too vigorous.
Q. Okay. When you see exam, palpable mesh through the anterior compartment wall, and then an assessment of pelvic mesh erosion, doesn't a mesh erosion mean it's

Page 23

coming through the pelvic -- through the anterior compartment wall as opposed to just being palpable?
A. So, in my experience, you can have a palpable erosion and you can have a visual erosion. So a palpable erosion is with a gloved finger you can actually feel the edges of the mesh, depending on the color or the appearance of it, that you couldn't see with the speculum and the naked eye.
Q. Okay. So erosion/exposure typically I associate with mesh coming through the tissue and being exposed so that it could be seen with the naked eye. Is that different from what you have with an erosion or exposure?
A. Those don't all go together. So there's a way to have mesh eroded so that your best efforts to look with the speculum you can't actually see it because of the geographic location and the speculum disallows you from being able to see it, but when you put your finger in, you can palpate raw edges of mesh. So you can have an erosion and not see it.
With a speculum exam, you might be able to see -- you can feel it and you might be able to see it if you put a cystoscope in the vagina and co-opt the vagina, for example. You can't always see it.

Page 24

Q. Okay. Are you able to tell from your review of the medical records whether the mesh erosion could be seen or merely palpated?
A. So on exam, it says palpable mesh through anterior compartment wall, thick ridge, no prolapse. In the assessment of mesh erosion, I could see the surgeon saying that he or she is assessing mesh erosion because of the palpation, not the visual.
Q. But you're not able to tell from the medical records whether it's visible, as in gone through the tissue, or whether it's only palpable, meaning you felt it through the tissue; is that fair?
A. I just have to go with Dr. Halcomb saying, "I can palpate raw edges of mesh," and, in fact, when you put your finger in, you can actually feel the points of the mesh edges through.
Q. Does it say you can palpate raw edges of mesh, or just palpable mesh?
A. I'm telling you I can palpate raw edges of mesh, so I see that if the surgeon is saying he or she palpates it, that may be what they're thinking of.
Q. But you don't know?
A. I don't know that for a fact.
Q. Thank you.

Page 25

A. In that case.
Q. Okay. So Dr. Halcomb referred Ms. England to Dr. Zimmerman?
A. Yes.
Q. And Dr. Zimmerman examined her on December 29, 2014?
A. Correct.
Q. And down under exam, it says "pinpoint exposure of Prolift material." What does that mean?
A. So that means when Dr. Zimmerman looked, he can see a small area through which he can see mesh, which he called the Prolift mesh.
Q. "Impression. Exposure/erosion of urogynecology graft material. Plan. Cystoscope and revise the exposed area of the mesh."
Why is it important to revise a pinpoint exposure of Prolift material?
A. So the mesh is exposed into the vagina. The doctor is assessing that that mesh erosion is the cause of her pelvic pain and he's proposing to excise that eroded area so as to remove the source of what he considers to be the source of her pelvic pain.
Q. So is it your judgment that Dr. Zimmerman considered this pinpoint exposure to be the source of

Page 26

her pelvic pain?
A. That is my judgment.
Q. Okay.
A. He remarked that there was thickness/stiffness of the anterior vaginal wall, tenderness in the right mid to apical anterior vaginal wall, and exposure, which he probably, when he put it all together, he said that's the cause of her pain.
Q. Okay. So on January 20, 2015, Dr. Zimmerman conducts his first revision procedure?
A. I see that.
Q. And was that in the office, or was that under anesthesia?
A. I can't tell here. I would -- I would say that because of the cystotomy repair it would have to be -- have been done under anesthesia. I don't think a surgeon would be doing this type of intervention in the office.
Q. Okay. And a cystotomy is what?
A. A tear in the bladder or a cut in the bladder.
Q. And the cystotomy occurred during the mesh removal process; correct?
A. Yes, they occur. And I've seen them occur personally when the mesh is deeply imbedded in the

Page 27

bladder muscularis and underneath the mucosa. Trying to remove it will cause a tear.
Q. You don't know how this cystotomy occurred, do you?
A. We could look at her record. Let's see.
Mesh transcending under -- transcending bladder muscularis. If that statement is made, then what that means is that when that mesh was removed the bladder muscularis was injured and that's where the cystotomy occurred.
Q. Do you know how the cystotomy occurred other than your review of the medical records?
A. I wasn't there, so I wouldn't know.
Q. Exactly. That's my point. Do you know what the circumstances were for Dr. Zimmerman to put a hole in her bladder?
A. Yes.
Q. What were they?
A. The mesh is transcending in the bladder muscularis. He removed the mesh. The bladder muscularis got interrupted, and that caused the cystotomy.
Q. How do you know that the cystotomy occurred when he removed the mesh from the bladder?

Page 28

A. It's the only way that it could happen.
Q. It could be an error in surgical technique?
A. That is possible but highly unlikely given the setting that the mesh was deeply embedded in the bladder muscularis.
Q. Do you agree that a cystotomy is a risk of any pelvic floor surgery?
A. We say that to our patients. Low risk, but a risk.
Q. And that's a risk that's also contained in the Instructions for Use?
A. I believe it is, yes.
Q. Okay.
A. In the Instructions for Use for the TVT-O, and I believe also the Prolift. We can look at that in detail if you like.
Q. Right. I think we understand that.
The development of fistulas is also a known risk for all pelvic floor surgery; correct?
A. That is correct. Different risk profile depending on the procedure, but a risk --
Q. And the development of fistulas is also a risk of --
MR. TARASKA: He wasn't quite finished.

Page 29

MR. THOMAS: Oh, I apologize.
THE WITNESS: I forget what I was saying.
MR. TARASKA: Do you want to read it back? You just overspoke the last three words.
MR. THOMAS: I didn't mean to interrupt, Joe. Sorry.
(The following answer was read by the reporter:)
A. That is correct. Different risk profile depending on the procedure, but a risk --
THE WITNESS: Depending on whether you're doing native tissue repair versus mesh surgery, versus anterior versus posterior repair. For example, in a posterior repair, the cystotomy risk is low. In an anterior repair, it's a little bit higher. In an anterior repair with mesh excision, it's even higher.
BY MR. THOMAS:
Q. And the development of fistulas is a risk that's contained in the Instructions for Use?
A. I think we agreed on that.
Q. I didn't remember if we had or not. I know we had for the cystotomy.
A. Yeah.

Page 30

Q. But also the fistula?
A. So I would say yes, and I think we have to agree that there are different IFUs that go with different periods in time, and so you would want to match the IFU of this period of 2006 with the risk profile here, because I know the IFUs changed at different points as people learned more about the complication risk profile.
Q. If I suggested to you 2006 -- and, actually, it should probably even be -- well, it is 2006. The cystotomy occurred in 2012; correct?
A. As a result of a 2006 placement.
Q. 2015. I'm sorry.
A. That would be governed by the 2006 IFU.
Q. I'm not going to argue with you.
A. I apologize. I'm just trying to be clear.
Q. And you are. I'm thinking about too many things.
A. Must be having too much fun.
Q. Was the January 20, 2015, procedure successful?
A. Well, the diagnosis was not given, so I would judge success based on the cure of the diagnosis. I would go back and say the impression was exposure/erosion of gynecology graft material and the

Page 31

plan was to revise the exposed area of mesh.
According to this, I would say that he was successful, because he did revise the exposed area of mesh, if that was his intention.
Q. Is there any way to tell what mesh was taken out in this procedure on January 20, 2015? Is it just Prolift mesh?
A. The doctor described "attempt made to remove all available Prolift material. Deep, superficial lateral arms transected."
That implies to me that since he didn't talk about the suburethral area that he did not operate in the geographical neighborhood of the TOT mesh.
Q. Okay. The doctor doesn't make any reference he did not excise any TVT material, you're deducing that from the records; is that fair?
A. I'm looking at his words. "Attempt made to remove all available Prolift material. Deep, superficial lateral arms transected. Mesh was bunched. Mesh transcending bladder muscularis."
All of this geographic activity was not conducted in the area of the midurethra, which is where the TOT -- the TVT-O would be.
Q. It says the mesh was bunched. What does that

Page 32

mean?
A. Yeah. The mesh is described as being intended to lay flat underneath the tissues, and so you would expect that if the mesh is laying flat there would be one layer of unfolded synthetic material underneath the bladder. What we have seen is that sometimes the mesh material, over time, when you go back to get it, is folded over and crumpled on itself, and that is described as bunching.
Q. Can it also be a problem with placement?
A. Can it? So is it possible? So there's a way to take the mesh and fold it over and then implant it, in which case it would be folded over, but the likelihood of flat-placed mesh as described by a surgeon being bunched as a result of surgical technique is extremely low.
Q. Okay. You don't -- you've not seen the mesh that was bunched; correct?
A. I did not see it for this particular patient.
Q. Yeah. Is there any explanation given in the medical records about whether the mesh was bunched over time or whether it was bunched during placement?
A. There's no way to know that from this description.

Page 33

Q. Okay.
MR. THOMAS: Is the mesh removed from Ms. England available for analysis, do you know?
MR. TARASKA: You mean today?
MR. THOMAS: Uh-huh.
MR. TARASKA: Not to my knowledge. Do you want me to check?
MR. THOMAS: Just curious. Yes.
MR. TARASKA: Okay.
MR. THOMAS: And I apologize for not knowing enough about this case, but typically the meshes are removed and then sent and analyzed by different people.
MR. TARASKA: I don't think so, but I'll check for us.
MR. THOMAS: Thank you.
BY MR. THOMAS:
Q. But you've not seen it and not been -- not asked to see it, I guess?
A. I did not look at any explanted material from this patient.
Q. Okay. Following the procedure with Dr. Zimmerman on February 12, 2015 -- excuse me. Strike that.

Page 34

Following the procedure with Dr. Zimmerman on January 20, 2015, there were a couple of postop visits?
A. Excuse me. Just bear with me for a second.
Q. Sure.
A. 1/20/2015.
Q. I'm on page 20 and 21.
A. 20, 21. Okay. Postop visit Dr. Zimmerman. Three weeks. Yes.
Q. Anything remarkable about the postop visit on February 12?
A. Complaint of bladder spasms and then a quarter-sized granuloma bed in the anterior wall, mesh filaments are seen in the apical right side of the bed, the bladder wall is intact, tenderness in the area of healing to palpation is what I see.
Q. And what's remarkable about the exam, in your opinion?
A. There's -- three weeks postoperatively, I still expect to see healing. I wouldn't expect to see mesh filaments in the right apical part of the bed.
Q. Would those be Prolift mesh?
A. Well, it is anterior and it's apical, which means it was not the transobturator, and then it would have to be the Prolift.

Page 35

Q. Okay.
A. Assuming that she had no intervening procedures to implant more mesh.
Q. Well, there's no record of any intervening procedures; correct?
A. That's my point.
Q. And the plan is to continue some medications, and then there's a preop on April 2, 2015; correct?
A. Yes.
Q. And "dry," is that vaginal dryness? Is that how you --
A. That's how I would interpret that.
Forgive me. "Dry." Dry could mean not leaking, as in no urinary incontinence, or vaginal dryness, and it's unclear from this.
Q. Okay. And as you look at "vaginal pain," it says "deep, central vaginal, persistent"?
A. Correct.
Q. What does that mean to you?
A. The patient is describing that the vaginal pain is deep inside the vagina in the midline. Persistent means it's not going away, it's always there.
Q. And where is that related to the implants that she had? Which implant is that related to, if you're

Page 36

able to tell?
A. So deep would imply the Prolift. Central vaginal, persistent would -- well, deep and central vaginal would imply the Prolift.
Q. Okay.
A. Near the opening would imply the TVT-O.
Q. So as you read the medical record entry on April 2, 2015, it's your opinion that he's referring to mesh from the Prolift that's causing these symptoms?
A. That is what I would conclude based on what I'm reading.
Q. And so then we go to Procedural No. 3 on April 22, 2015 --
A. Yes.
Q. -- where there's excision of urogynecological mesh and a cystoscopy?
A. Correct.
Q. Was that procedure successful?
A. If we look at what the plan was, it's mesh excision under anesthesia, and he described excision of urogynecologic mesh, and so I would have to say that the procedure was successful because he did what he planned to do.
Q. Was this in the office, or was it in the

Page 37

operating room, do you know?
A. It says mesh excision under anesthesia would be the plan, and I don't know of any surgeons that would attempt this extent of surgical activity without anesthesia.
Q. Under findings for the April 22 visit, it says: "2-centimeter area of mesh exposure in anterior vaginal wall 10 o'clock to 2 o'clock."
Does that give you enough information to determine which mesh was removed?
A. Yes.
Q. What does that tell you?
A. So usually when surgeons talk about the anterior vaginal wall they're talking about the proximal vaginal wall, not the bladder neck, and since the Prolift would have been placed in the proximal anterior vaginal wall, I would think that he's talking about the Prolift.
Q. All right. And "permanent suture at the level of the trigone," what does that mean?
A. That means that the surgeon cystoscopically is looking and seeing suture in the trigone through the bladder.
Q. And which mesh, if either, would that apply to?

Page 38

A. So at the level of the trigone the suture -- the mesh filaments actually look like suture because of the shape and so forth. At the level of the trigone, the only thing that would be there would be Prolift.
Q. Okay. So nine days later is a postop visit with Dr. Adam. Do you see that?
A. Yes.
Q. "Significant urinary leakage since last night. Increasing suprapubic pain. Severe nocturnal enuresis last night. Insensible urine leaks throughout the day."
What is enuresis?
A. Urine coming out without knowledge. And nocturia, you wake up wet, basically.
Q. Got it. So this is when Dr. Adam, anyway, his impression is that she has a vesicovaginal fistula; correct?
A. That's what he says.
Q. What is a vesicovaginal fistula?
A. So "vesico" is -- "vesi" means bladder. "Vaginal" means vagina. Fistula is abnormal connection. So you could sound this out as an abnormal connection between the bladder and the vagina. It's a hole.
Q. What's the result of a vesicovaginal fistula?
A. Significant urine -- copious amounts of urine

Page 39

in the vaginal vault. So urine, instead of coming out the urethra, goes through the opening of the fistula and ends up in the vagina, and it's uncontrolled.
Q. Are you able to tell from your review of the medical records how that happened?
A. Yes.
Q. How did it happen?
A. I believe that the vesicovaginal fistula occurred as a result of the dissection of the deeply embedded anterior wall mesh that transgressed into the bladder such that when it was dissected out the hole was -- occurred.
Q. And that would have been from the January 20, 2015, procedure?
A. It could have been from any of the procedures subsequent to Dr. Yang's initial procedure.
Well, the first surgery from Dr. Zimmerman, Procedure No. 2, where the mesh was dissected out and the cystotomy was repaired on 1/20/2015, the fistula was discovered at 5/1, about four months later. It could have been just the cystotomy repair broke down over that four-month period, or it could have been related to Procedure No. 3 in which there was mesh circumscribed and dissected out.

Page 40

Q. Do you have an opinion based on your review of the medical records as to which procedure caused the vesicovaginal fistula?
A. I couldn't say.
Q. Anything about the location of the vesicovaginal fistula relative to the two procedures that allows you to have an opinion in that regard?
A. Both procedures occurred in the same neighborhood, as near as I can tell, geographically speaking, so either of them could have been responsible. If you want to look at the one that was closest to the discovery of the fistula, it would have been the third procedure done by Dr. Zimmerman.
Q. When you say "closest," you're talking about in time?
A. In time. Proximity.
Q. Not in geography?
A. The geography appeared to be the same in both cases.
Q. For either the January 20, 2015, or the April 22, 2015, procedures, is there any suggestion that her prolapse has returned?
A. I don't see anything in the diagnoses that says prolapse has returned.

Page 41

Q. Is there any suggestion in the medical records for the January 20 procedure or the April 22 procedure that her stress urinary incontinence has returned?
A. I don't see any mention of stress incontinence or prolapse in either of those dates.
Q. So Dr. Adam takes over on May 6, 2015. Do you see that?
A. I see a procedure with Dr. Adam, yes.
Q. Do you know why Dr. Adam took over?
A. I wasn't there, so I wouldn't know.
Q. Have you read any of the depositions that would suggest to you why?
A. I don't recall seeing in a deposition why the take-over happened. I suspect that Dr. Adam is a urogynecologist more senior and more experienced than Dr. Zimmerman who has expertise in repairing vesicovaginal fistulas and reimplanting ureters and so forth and that's the reason why Dr. Adam took over.
Q. And Dr. Adam, on May 6, 2015, attempted to repair the vesicovaginal fistula?
A. "Procedure." Say again. The date?
Q. May 6, 2015.
A. He didn't attempt to repair it then. He performed a cystoscopy in an attempt, which is what I

Page 42

would do, to map the vesicovaginal fistula.
Q. Okay. Anything else remarkable about the cystourethroscopy on May 6?
A. He noted there was a 1-centimeter vesicovaginal fistula above the interureteric 1 centimeter from the right ureteric orifice. He thought he saw possible mesh erosion into the trigone and mesh erosion at 1:00 o'clock to the right ureteric orifice.
Q. And the possible mesh exposure into the trigone area and the area of small mesh erosion at 1:00 o'clock to the right UO, what is right UO?
A. Ureteric orifice. It's the tube that brings urine from the kidney.
Q. Is that the Prolift, or is it the TVT-O?
A. In that location, it would not be the TVT-O. It more likely is the Prolift.
Q. On May 14, Dr. Adam does attempt to repair the vesicovaginal fistula; correct?
A. So he describes an exploratory laparotomy, he catheterized the ureters, and he talks about a repair with omental flap.
Q. And what's the significance of a repair with the omental flap?
A. In the past, many of these fistulas, when they

Page 43

occurred, occurred as a result of radiation to the pelvis and they were -- they had a hard time getting these fistulas to heal because of insufficient blood flow. So the theory behind the omental flap is if you brought down a piece of omentum, which is a very highly vascularized tissue, and you interposed it between the repair of the bladder opening and the vaginal opening that the blood flow would help heal the attempt at repair. And this is what Dr. Adam applied here in an attempt to ensure that the fistula would -- once closed, would stay and heal.
Q. Do you agree with that procedure?
A. It's a standard procedure that's used by urogynecologists and urologists.
Q. It says "vaginal and bladder mesh excision." Are you able to tell whether that mesh that was excised in the May 14 procedure was Prolift or the TVT?
A. From this explanation, I do not have a geographic location. However, if the mesh is being excised from the bladder, it is more likely to be from the Prolift. I'm not sure about the vaginal side, if there were reflections of the same material. So I'm pretty sure, from the bladder side, bladder mesh excision is referring to the Prolift.

Page 44

Q. Under findings, a 1-centimeter supratrigonal fistula, just to the right of midline, is that the same location as the prior fistula?
A. Well, "prior." This is the same fistula.
Q. It's the same fistula?
A. Well, you know, Dr. Adam talked about the fistula that he identified on cystoscopy.
Q. Got it.
A. And so it looks like he's talking about the same fistula from 5/6/2015.
Q. Are you able to tell from this description how it relates to the hole that Dr. Zimmerman put in the bladder with his first revision surgery?
A. Well, let's go back to that. Dr. Zimmerman. A cystotomy occurred. He doesn't give me a geography in his 1/20/2015 surgery, so I don't know where that opening is.
Q. Okay. It also says "bunched up mesh on the right with detrusor muscle, adjacent to right ureter"?
A. So we're back to Dr. Adam on 5/14?
Q. Yes. Page 24. Right in the middle of the page.
A. "Bunched up mesh on the right within the detrusor muscle." Again, the mesh is embedded into the

Page 45

bladder muscularis and adjacent to the right ureter.
Q. And, again, is that the Prolift?
A. Very -- yes.
Q. Anything remarkable about the technique that was used?
A. I think he did a standard technique for an open fistula repair.
Q. Towards the end of the description of the procedure, you say "cystotomy repair was continued."
Does that give you any information to suggest that he was repairing the initial problem created by Dr. Zimmerman, or is cystotomy the same thing as fistula?
A. So let's look there. Fistula located after he opened the bladder. 1 centimeter from the right ureteric orifice. 1.5 from the left ureteric orifice. Fistula tract was removed with care taken to avoid ureters. A sheet of mesh was seen in the detrusor muscle on the right. The mesh was dissected off the detrusor muscle and the epithelium. 1-by-2-centimeter mesh excised. The epithelium was mobilized on the vaginal side. Mobilized for bladder closure. Small piece of mesh excised from the left side. Mobilized -- bladder closed. Mesh palpable on right close to ureter.

Page 46

Right ureter was reimplanted. Bowel repacked. So forth. Neocystotomy. Neocystotomy and spatulated -- Foley changed to three-way. Cystotomy repair was continued.

What this implies to me is that he partially completed the cystotomy repair, went ahead and reimplanted the ureter, and then continued with the repair.

Q. So we've seen vesicovaginal fistula and we've seen cystotomy. Are those synonymous?

So when he's repairing the cystotomy, is he repairing the hole that Dr. Zimmerman put in the bladder in the very first procedure?

A. So in order to do the repair of the vesicovaginal fistula, you'll notice along this dissection he said a clamshell opening of the bladder. He actually put a cystotomy in in order to get to the area to repair it. So it was an intentional cystotomy so he can actually see.

Because normally when you go in, to look down you're actually seeing the front part of the bladder. The problem is behind. So many surgeons, to get to that area, will actually open the bladder so they can see the defect. So it's like coming through the roof here to

Page 47

look at a defect in this table, fixing it, as opposed to going underneath.

Q. Dr. Zimmerman's cystotomy was inadvertent?

A. Correct.

Q. Dr. Adam's cystotomy was intentional in order to complete the procedure?

A. Correct. And that's a standard of care technique. It's employed by many urologists and urogynecologists.

Q. And following this procedure by Dr. Adam -- it was not successful; is that correct?

A. Well, let's see. The intent for Dr. Adam in Procedure No. 5 is vesicovaginal fistula repair with omental flap, mesh excision, and reimplant the ureters. At the end of that procedure, there was urinary -- so we're going to 6/12, which is follow-up from that procedure a month later. There's urinary leakage. The patient believes it's transurethral. May we move on?

Q. Sure.

A. So bladder spasm. Physically active. Medications. No evidence of recurrent vesicovaginal fistula.

So based on this visit of 6/12/2015, I believe that the repair from 5/14, at least a month later, was

Page 48

holding.

Q. Okay. Let's go down.

A. Which means it was successful.

Q. Go down to 12/20/2016. Dr. Adam again says that there's a recurrent vesicovaginal fistula.

A. So a month -- a year -- 5/14 to 12/20, so that's 18 months later, he's saying that there's a vesicovaginal fistula that's recurring.

Yes. So at some point his repair, which seemed to have been intact a few months later, 18 months later was no longer intact.

Q. What explanation do you have for a recurrent vesicovaginal fistula like this?

A. They're very, very -- oh, sorry.

Q. Go ahead. I finished.

A. They're extremely difficult to repair and stay repaired because of the location, the thinness of the tissues involved, and the fact that to do the repair you have to put tissues under tension, and tissues do not repair well when they're under tension.

Vesicovaginal fistulas historically have been very difficult to keep intact when you repair them, so I'm not surprised that he had to come back.

Q. And do you have any medical records for

Page 49

Ms. England since December 2016?

A. These are -- I believe these are all the records I have. One of our patients I got sent a second -- a subsequent set of medical records, which I reviewed, but they were mostly primary care. So I don't have any records, I know this, for this patient, that's related to pelvic floor issues.

Q. Okay. So it's fair to understand that your analysis of her medical records insofar as you reviewed her complaints in this case ends on December 20, 2016?

A. That's what I can say.

Q. All right. Now, it's fair to understand that there are no complaints of a cystocele or a rectocele in the medical records since the implant on November 22, 2006; correct?

A. I have not seen any further recurrences of cystocele or rectocele.

Q. And there's no mention of stress urinary incontinence in the medical records since the implant on November 22, 2006; agree?

A. I would agree that we haven't seen that. However, it's going to be difficult to document stress incontinence, or notice it, if there's a fistula, because that's the low -- the resistance path would be

Page 50

the fistula, so you wouldn't know.
Q. Do you agree that there's been no complaint of dyspareunia or vaginal pain in the medical records since 2015 at the time of the diagnosis of the atrophic vaginitis?
A. Say the date, please.
Q. Yeah. 2015.
A. 23? 22? 21?
Q. 22.
A. Vaginal pain, inflammation. I'm going to tell you up front that this patient probably wasn't going to be pain with dyspareunia. It was going to be the leakage related to the fistula. So she's very unlikely going to be talking about dyspareunia, because she's probably going to be focused on the leakage. So, correct, no documentation.
Q. Based upon going through the procedures that we've just discussed, we didn't identify anytime, based on your review of the medical records, that the TVT-O was removed; fair?
A. I'm going to say yes, there's nothing related to that.
Q. Do you have any opinion that the TVT-O caused any of the symptoms that she presents with?

Page 51

A. Well, I -- let me look, please.
I don't have anything that says that palpation of the TVT-O replicated her symptoms of pain and so forth. And reference keeps being made to a tender anterior wall spanning foreign body. So I don't think that there was a specific treatment of the TVT-O sufficient here for me to point to that, because the primary focus for this patient has been addressing the fistula.
Q. All right. So is it fair to understand that you do not have an opinion in this case that the TVT-O caused any of the symptoms or complaints that Ms. England makes in this case?
A. Just give me a moment.
So I'm very clear that I see complications related to the Prolift, but to go along with your line of questioning, I don't see anything specific that I can point to as a TVT-O. My best understanding is she still has the TVT-O in place, and my best understanding also is that I can't really talk to her TVT-O-related symptoms, because the focus in front of us right here is the Prolift and the fistulas that was caused by it.
Q. Just to be clear, it's fair to understand that you do not have any opinions that the TVT-O implanted in

Page 52

Ms. England caused any of the problems or symptoms that are the subject of her complaint in this case; is that true?
A. So symptoms. Fistula, mesh erosion into the bladder/vagina, recurrent pelvic pain radiating down legs, that could be either Prolift or TVT-O. Recurrent rectal and sacrum pain, I don't know the answer. Rectocele, no. Dyspareunia, possibly.
Q. Do you have an opinion to a reasonable degree of medical certainty that the TVT-O caused any of the symptoms about which Ms. England complains in this case?
A. I'm actually looking through here. I can't see it today.
Q. Okay. Isn't the primary driver of all the procedures subsequent to the initial revision surgery the attempts to repair the hole that Dr. Zimmerman placed in Ms. England's bladder in the first procedure?
A. I'm sorry. Say that again.
Q. Isn't the primary driver of the revision procedures after the first Zimmerman procedure to repair the fistulas?
A. The procedures that are subsequent here are repairing fistulas and extracting mesh, removing mesh. The fistula happened as a result of the Prolift mesh

Page 53

being embedded. The subsequent procedure was to remove Prolift mesh because it caused her -- it was symptomatic for her. As a result of that, there was a hole, and that led to the subsequent surgeries.
Q. Okay. And the hole in the bladder can occur with any midurethral sling; correct?
A. No.
Q. It cannot?
A. Well, the hole in the bladder is in the bladder. A midurethral sling hole would be at the bladder neck or distal, because that's where the midurethral sling passes.
Q. So there's no risk of a cystotomy with a midurethral sling?
A. Not this kind of cystotomy. Retropubic slings require cystoscopies because sometimes the retropubic sling can traverse the anterior aspect of the bladder dome, which is different than this area.
Q. But you can have a cystotomy with a retropubic sling?
A. It's highly unlikely because of the trajectory of the retropubic sling in this area. So between the -- we're talking about between the vagina and the bladder. The likelihood of a cystotomy there is low. The

Page 54

likelihood of a cystotomy at the lateral aspects of the anterior dome is present with retropubic slings.
Q. Okay. Wherever you have the cystotomy, there's a risk of cystotomy with any kind of midurethral sling; correct?
A. Well, I'll give you this: One of the things that people advertise with transobturator-type slings is that the need for cystoscopy is at the discretion of the surgeon because the risk is lower. That's one of the arguments that people make for TOTs. So TOTs tend to have a lower risk for cystotomy, I think was your question.
Q. Yes, that's fine. The risk of cystotomy can happen with a Birch procedure?
A. Absolutely.
Q. The risk of cystotomy can happen with a Kelly plication?
A. Very low possibility.
Q. And can cystotomy occur with a sacrocolpopexy?
A. Yes.
MR. TARASKA: When you get to your natural stopping point, we're over an hour now.
MR. THOMAS: Do it?
MR. TARASKA: Do you want to do it?

Page 55

MR. THOMAS: Yes.
(Recess from 1:07 p.m. until 1:14 p.m.)
BY MR. THOMAS:
Q. Doctor, had Ms. England had a sacrocolpopexy in 2006 as opposed to a Prolift, could she have suffered the same mesh exposure issues as she did with the Prolift?
A. So sacrocolpopexy has a 3 to 5 percent risk of mesh exposure. Smaller risk of exposure into the bladder. Certainly vaginal exposure. Yes.
MR. THOMAS: I have to hear my question again to make sure I understood the answer.
(The following question was read by the reporter:)
Q. Doctor, had Ms. England had a sacrocolpopexy in 2006 as opposed to a Prolift, could she have suffered the same mesh exposure issues as she did with the Prolift?
MR. TARASKA: I'm sorry. Could you read that again?
(The following question was read by the reporter:)
Q. Doctor, had Ms. England had a sacrocolpopexy in 2006 as opposed to a Prolift,

Page 56

could she have suffered the same mesh exposure issues as she did with the Prolift?
MR. TARASKA: So form.
BY MR. THOMAS:
Q. And so there's nothing about the Prolift as compared to the sacrocolpopexy in 2006 that would have precluded mesh attaching to the bladder which would require a revision as Dr. Zimmerman did in 2015?
A. Different geographical location. Sacrocolpopexy exposure would be more likely to be near the apex or the upper vagina and the upper bladder dome, which is much more accessible abdominally for repair. The repair profile would have been dramatically different.
Q. In the instance of a mesh erosion or a mesh exposure involving sacrocolpopexy, there's a risk of cystotomy?
A. So the question is during the repair of an erosion --
Q. Yes.
A. -- is there a risk of cystotomy?
Q. Let me ask it again. I'm sorry. You're exactly right.
Doctor, you agree that the use of mesh in a

Page 57

sacrocolpopexy presents a risk of mesh erosion or mesh exposure?
A. Mesh is a foreign body and its use carries a risk of mesh exposure and mesh erosion.
Q. And to the extent that there is a mesh erosion and a mesh exposure and a decision is made to repair that mesh erosion or mesh erosion, there is a risk of cystotomy?
A. So if the mesh is eroded into the vagina, repairing the mesh erosion involves dissecting the mesh off of the vagina abdominally and reclosing the vagina. The risk of cystotomy in that setting is extremely low.
If the erosion is into the bladder, then, by definition, in order to repair that erosion, you have to lift the bladder off the mesh in order to reclose it, and that is equivalent to a cystotomy, but it's not a cystotomy that you made. It exists because of the exposure.
Q. And to the extent that there's a cystotomy that turns into a fistula -- strike that.
There is nothing about -- let me start over again.
Doctor, to the extent that Ms. England had had a sacrocolpopexy in 2006 as opposed to the Prolift, is

Page 58

there anything about that procedure that would have prevented her from having a revision surgery of the sacrocolpopexy mesh that would have resulted in the fistulas that she later had?

A. Let me see if I can bust the question up so I can answer it. If she had a sacrocolpopexy in 2006 and it eroded --

Q. Yes.

A. -- is there a risk that that erosion would lead to a fistula?

Q. Correct.

A. There is a risk, an extremely low risk of fistula formation, but whenever you repair the bladder in proximity to the vagina in the place where the bladder and the vagina are and share a wall, there is a risk of a fistula.

Lifting the bladder off the sacrocolpopexy mesh, repairing an erosion, would require that doc to basically bring that peritoneum around to isolate the repair suture line from the sacrocolpopexy mesh, which is what we do when we have a sacrocolpopexy mesh exposure into the bladder.

Q. Doctor, do you have an opinion about what it is about the Prolift that caused these erosions or

Page 59

exposures?

A. Yes.

Q. What is it?

A. When you take a foreign body and you place it transvaginally, you cannot fully sterilize the vagina, as I've pointed out in my reports. There's a constant bacterial load in the vagina even in the midst of full attempts at sterilization. So by placing extensive amounts of mesh transvaginally as you do with the Prolift, you are basically bringing contaminants and vaginal fluids into the repair area.

Then when you anchor the Prolift in a side-to-side fashion as is the case with Ms. England, you actually put traction on the arms. The arms of the synthetic mesh have a different characteristic once you put them under traction, because that's the way you place them. They are much more prone to creating painful scars, and because of the bunching up, as we've seen from the descriptions, they create a higher risk of nonhealing vaginal tissue and erosions as well as bladder misbehavior in terms of, like, erosions or bunching.

The placement technique for the Prolift and the large mesh load that's placed with the Prolift and the

Page 60

fact that the arms are placed -- you have to pull the arms through in order to get them placed -- creates an environment in the vagina that makes them prone to erosion.

Q. Is there any different risk that the Prolift presents to a patient different from the risk that is presented by the mesh used in sacrocolpopexy, or is it just a matter of quantity?

A. Dramatic difference.

Q. What is the different risk?

A. The sacrocolpopexy mesh is placed through a clean environment. The transvaginal Prolift mesh is placed through a contaminated environment. The anchoring of the Prolift mesh is a side-to-side transverse anchoring that involves scarring into the pelvic sidewalls, pelvic floor muscles, such that when the mesh contracts it actually pulls the muscles to the midline as it heals, in addition to the bacterial and vaginal fluid contamination.

It's a different animal compared to when you place a sacrocolpopexy mesh vertically. When that mesh contracts, it pulls the vagina upwards and lengthens it more.

Q. But the risk is the same, that is, the risk of

Page 61

exposure or erosion; correct?

A. No, absolutely not.

Q. How is the risk different? Tell me that.

A. So when you -- let me reiterate. When you place a synthetic polypropylene mesh through the abdomen as we've been doing since the 1960s, it's placed through a clean environment that's fully sterilized. When you place that same polypropylene material through a contaminated environment that is not completely -- that is not completely sterilized, you bring vaginal fluids and bacteria along with it.

When you place a sacrocolpopexy mesh, you place it vertically through the abdomen. When it contracts, as it does when it heals, as all foreign bodies -- meshes do, it pulls the vagina upward to fully lengthen it. When the mesh placed with a Prolift contracts, it pulls the vaginal walls inward to what's the midline, causing pain and contractures.

It's a different route for the same material. The route is different, and that makes a huge difference.

Q. You mentioned earlier in your deposition that you wanted to update your report to refer to, I believe, her prognosis?

Page 62

A. Correct.
Q. What is the change that you'd like to make?
A. It is not a change. It's an augmentation. I have noted that her prognosis is uncertain. I want to emphasize that, as a physician, my job is to provide hope to patients. So I don't give up if the patient doesn't give up. We keep looking for ways to make their symptoms better and improved.
In the case of Ms. England, it is more likely than not that her injuries and her symptoms will be permanent, not temporary.
Q. Let's talk about that. Are the symptoms you're referring to on page 27 of your report?
A. Urinary retention, we don't have the ability to evaluate that right now because the last thing we did was look at her fistula repair, so we don't know what that is.
Q. I don't mean to interrupt you.
A. Sure.
Q. I direct you to page 27. Are the symptoms that are present on page 27 those that you claim are ones that you can't treat?
A. I didn't say we can't treat them.
Q. Unlikely to be successful?

Page 63

A. Her symptoms are likely to be permanent.
Q. Got it. So are these the symptoms to which you're referring on page 27?
A. Let's look at them. I see new symptoms/problems since TVT-O/ Prolift procedure. I have a list there. That's the list that I'm going through with you.
Q. Good. Is that a good place to go?
A. So there's there, and then there's the -- so we've got areas in 27. If you want to go through with me line by line, I'll tell you.
Q. What I'd like to know is what it is that you claim that she experiences in 2019 that you can treat which you're unlikely to be able to be successful in treating.
A. That's what I'm going through with you.
Q. Thank you. Good.
A. So the urinary retention, we're not going to know about that until the fistula is completely healed.
The fistula, we've seen that it's recurred already multiple times. We don't know if this is going to recur or not. The likelihood of the fistula recurring is high.
The mesh erosion into the bladder. She still

Page 64

has multiple arms of transvaginal mesh remaining in her groins and pelvic tissues. The likelihood of those meshes eroding again is high, again.
Q. Why?
A. Because mesh keeps eroding, as you've seen in these cases. There's been multiple surgeries in an attempt to remove things, and the doctor comes back later and says, "Oh, yeah, there's another piece." That keeps going on as long as there's mesh remaining in the body in proximity to surface tissues.
Recurrent vaginal/pelvic pain, onset 2014, radiating down to her legs, that is very likely to continue. That ain't going to be cured. The reason why we're not talking about it here is because the focus is on this lady's fistulas.
You have to revisit back this patient's complaints of pain. There was never a documentation that the pain was resolved. There's just been no complaints of it, because she wasn't asked because everyone's focused on her fistulas.
Q. Stop just a second there. I want to make sure the record's clear.
A. Sure.
Q. There's no record that she continues to

Page 65

experience vaginal/pelvic pain that radiate down her legs after 2014, is there?
A. You're absolutely correct, but there's no documentation that that has resolved, because she has bigger problems to contend with now. We're talking about fistulas and leakage. That's a bigger deal than "pain radiating down my leg." If the fistulas ever resolve, ever, then we go back to whether or not she still has. Nobody's asked her that.
Q. Okay.
A. Recurrent rectal and sacral pain, you know, we didn't talk very much about that, but the Prolift is a side-to-side spanning anatomically. This is arms of this mesh that is anchored from the left-sided pelvic side wall to the right-sided pelvic side wall. It's a very tight bow tie around the patient's rectum, which is very likely a cause of her rectal and sacral pain. I see these in patients a lot.
Q. When was the last time that was reported in the medical records?
A. That's what I'm saying. I'm just saying this was once reported. Nobody ever documented that this was cured. Nobody asked. There's no place where -- "Is your rectum and sacrum pain gone?" Nobody's asked that

Page 66

question.
Q. And there's no evidence that it continued either, is there?
A. Well, no, there's no evidence anybody asked her about it.
Q. Thank you.
A. Right. Rectocele is native tissue repair. Probably resolved.
Dyspareunia, I don't think that's likely to resolve. No one's asked her about that, again, because everyone's here focused on Ms. England's fistula.
And the last record we have is a fistula repair. Nobody's gone through and asked her are these symptoms still here.
Q. Okay.
A. So her vaginal dryness could be resolved, will be resolved with vaginal estrogen.
Urinary urgency, possibly resolved with vaginal estrogen if she's treated.
Vaginal pain and pelvic pain with sexual intercourse, I don't think so.
Q. Again, those are the same things we just talked about. There's no documentation of the last three in the last several years?

Page 67

A. Either way.
Q. Correct.
A. Right. Nobody's asked her about it.
Q. Anything else?
A. We went through the list, didn't we?
Q. I just want to make sure that you have an opportunity to address everything that you'd like to talk about in terms of her prognosis.
A. So the most important thing I want to tell you is the permanence of her symptoms.
Q. Okay. Any recommendation from you about her future care and treatment?
A. I would want to follow up and see what the status of her fistula is, because right now that's the most important and concerning issue with her. Once her fistula is resolved, I would seek to bring her in and walk through with her her list of complaints and see what's persisting and what's not, and I would gear treatment based on what the answers to those questions are, and that evaluation.
Q. Do you know how Ms. England was employed? Do you know what she did for a living?
A. I'm sure I do, because I did read her deposition, but, you know, lots of these ladies today

Page 68

were nurses, and I don't know -- I didn't put down what she did here for a living.
Q. Okay. Do you know the last time she took prescription pain medications?
A. I do not. I know she was on Lortab for migraine headaches is what I was -- is what I understood.
Q. Do you know where the current source, location, of her pain is today?
A. I do not.
Q. Do you know what the plaintiff understood about the risks of the surgery that she had in 2006?
A. I believe that she was explained that things could go wrong, and she probably went through the consent form as Dr. Yang -- this is Dr. Yang's patient -- had discussed with her. I don't have a recollection of what her understanding was.
Q. Do you know whether she had chronic pelvic pain in the 1980s?
A. Let's look. I'm looking at this patient who had a transabdominal hysterectomy with left salpingo-oophorectomy in 1988, probably performed for pelvic pain. That procedure will be curative if that were the case.

Page 69

Q. Do you know anything about her chronic pelvic pain in the 1980s other than your entry on page 14 about her prior history in 1988?
A. I do not. I do know in 2006 she denies bleeding, denies pelvic pain, status post hysterectomy with LSO. No abnormal symptoms. She didn't have pelvic pain on that visit.
Q. Other than the abdominal hysterectomy and the left salpingo-oophorectomy in 1988, do you have any other information about sources of chronic pain in the 1980s?
A. She had a cholecystectomy. That could cause pain.
Q. That was in 2006; correct?
A. I'm sorry. 2006. I apologize.
Q. Anything else?
A. There's nothing else that I have here from that.
Q. Do you know whether she had pain with intercourse in the 1980s?
A. I do not.
Q. Do you know if she was ever diagnosed with chronic pelvic pain in the 1980s?
A. I do not. I suspect with the abdominal

Page 70

hysterectomy and left salpingo-oophorectomy many of those procedures are performed as a result of pain with intercourse related to touching of the uterus during sexual activity, which is resolved when the uterus is removed.

Q. Do you know why Dr. Zimmerman didn't remove all the mesh during his first revision surgery?

A. Since I'm not Dr. Zimmerman, I would not. However, my understanding is that many docs are under the impression that if you only expose the -- remove the exposed mesh the patient is likely to be cured. I do not subscribe to that school of thought.

Q. So you would have done a different revision surgery than Dr. Zimmerman did?

A. When patients come to me with mesh exposure and mesh complications, my understanding and belief from my clinical experience is that the entire exposed mesh needs to be removed. I don't think that's a universally subscribed principle.

Q. When you say "the entire exposed mesh," are you talking about the area of the exposure or the entire mesh needs to be removed?

A. So I'm referring to the fact that mesh in one location has an exposure. That entire mesh needs to

Page 71

come out. If she has a mesh in that location, like a Prolift, and a TVT that's not exposed, I would leave the TVT alone and I would remove the Prolift.

Q. You would remove the entire Prolift for a small exposure?

A. And I say that because my experience is that if you don't, then the remaining areas, as we've seen with Ms. England, will continue to ex -- will continue to present as exposed.

And subsequent removal of partially removed mesh is much harder to accomplish than initial removal of the intact mesh. So you make life more difficult for the patient if you fail to remove the entire mesh that is having the complication.

Q. What is your understanding of the training, education, and experience of Dr. Yang with the Prolift and TVT-O?

A. This is my understanding from her deposition. She was trained in incontinence and prolapse procedures in her residency. She went to courses sponsored by Ethicon and what she described as major GYN societies for implantation of mesh. She did not have any specific training in mesh removal.

We're talking about Dr. Yang; correct?

Page 72

Q. Uh-huh.

A. But she reported performing a number of these mesh placement and TVT procedures. She also reported that she had training from one of her senior partners in her practice.

Q. Did you find her qualified to perform this kind of surgery?

A. I did not find her unqualified.

Q. Okay. Did you find from your review of her deposition that she was knowledgeable of the risks of pelvic floor surgery generally?

A. Yes.

Q. Did you find from a review of her deposition that she was knowledgeable of the risks of TVT-O?

A. Yes.

Q. Did you find from a review of her deposition that she was knowledgeable of the risks of Prolift?

A. Yes.

Q. And did you find from a review of her deposition that she was knowledgeable of the risks of native tissue repair?

A. I believe so, yes.

Q. Do you know whether Dr. Yang stands by her decision to implant the Prolift and the TVT-O in

Page 73

Ms. England?

A. I think there are parts of her deposition where she said she stands by it.

Q. Doctor, going to page 5 of your report, please, Exhibit 3 --

MR. TARASKA: By the way, I have a form objection that I simply missed, I'll just put it on now, as to what Dr. Yang's thoughts are about whether she stands by or doesn't stand by any earlier decision. One practitioner commenting on another. Go ahead.

MR. THOMAS: Okay. Sure.

BY MR. THOMAS:

Q. In the Ashbrook case, you say you review the general and product-specific literature related to the Gynecare TVT-O and Prolift products. I just want to make sure. That does not include any of the studies published in the literature about the safety and efficacy of either the TVT-O or the Prolift?

A. First, again, there's no definitive safety studies performed on the Prolift product. Generally speaking, in my background study of keeping up with my CME and just going along with my recredentialing, I'm obliged to follow the literature and keep up with it. I

Page 74

did not do that specifically for this case, but I did review the TVT-O and Prolift IFU and the methods of implantation in detail.

Q. Here's what I'm trying to avoid, and if I need to, I will. In the Ashbrook case, we decided that you were here for a case-specific report, you were relying on your clinical experience and not relying upon any of the published studies on the safety and efficacy of midurethral slings.

Is that the same in England for the TVT-O?

A. This is the same for the three depositions that we're doing today.

Q. And is it the same for the Prolift as well?

A. Absolutely.

Q. Thank you.

MR. THOMAS: Give me just a second. I might be finished.

(Discussion off the record.)

MR. THOMAS: I'm going to stop, Doctor. Thank you.

CROSS-EXAMINATION

BY MR. TARASKA:

Q. I just have a couple questions.

You mentioned that in your clinical practice

Page 75

you attempt to interview patients and evaluate them through physical exam; is that correct?

A. Yes.

Q. And that applies when you are treating the patient?

A. Correct.

Q. In this particular case, after reviewing the medical records of this woman, Mrs. England, do you feel that you have sufficient information upon which to base your opinions as you have provided them to us today and in your report?

A. I do.

Q. And do you feel that your opinions are within a reasonable medical certainty?

A. Yes.

Q. Sir, do you have any criticisms of the other physicians who have treated Mrs. England throughout her time since the implantation of these devices?

A. With respect to the physicians that I -- whose records I reviewed, I do not.

Q. Thank you, sir.

There's been a question about the fistula caused during Dr. Zimmerman's procedure, I believe. Do you recollect that line of questions?

Page 76

A. Yes.

Q. All right, sir. Do you have any criticism of the fact that a fistula was caused during that particular procedure?

A. Well, the fistula was not caused during that procedure. There was a cystotomy sustained as a result of attempting to dissect the mesh out from underneath the bladder. That cystotomy was repaired and that cystotomy over time evolved into a fistula, as they can.

Q. Do you have any criticism of the fact that what occurred during that procedure eventually evolved into a fistula?

A. I do not.

MR. TARASKA: Thank you, sir.

MR. THOMAS: I have nothing further. Thank you, Doctor.

(Whereupon, the deposition concluded at 1:43 p.m.)

Page 77

C E R T I F I C A T E

I, JOAN L. PITT, Registered Merit Reporter, Certified Realtime Reporter, and Florida Professional Reporter, do hereby certify that, pursuant to notice, the deposition of LENNOX HOYTE, MD, was duly taken on October 22, 2019, at 11:57 a.m., before me.

The said LENNOX HOYTE, MD, was duly sworn by me according to law to tell the truth, the whole truth, and nothing but the truth, and thereupon did testify as set forth in the above transcript of testimony. The testimony was taken down stenographically by me. I do further certify that the above deposition is full, complete, and a true record of all the testimony given by the said witness.

_____

JOAN L. PITT, RMR, CRR, FPR

(The foregoing certification of this transcript does not apply to any reproduction of the same by any means, unless under the direct control and/or supervision of the certifying reporter.)

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ACKNOWLEDGMENT OF DEPONENT

I, _____, do hereby acknowledge that I have read the foregoing pages, 1 - 81, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

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LENNOX HOYTE, MD DATE

Subscribed and sworn to before me this

____ day of _____, 20___.

My Commission expires: _____

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Notary Public



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